



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 13, 2022

Matthew Feinberg
Agent for Novozymes BioAg, Inc.
c/o Exponent, Inc.
1150 Connecticut Ave. NW
Suite 1100
Washington, DC 20036

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Add
expiration date; update fertilizer language
Product Name: Optimize® FXC
EPA Registration Number: 73314-25
Application Date: 03/02/2022
OPP Case Number: 00343802

Dear Mr. Feinberg:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration

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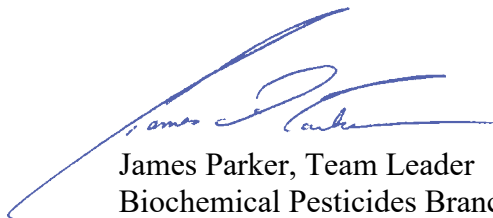
OPP Case No. 00343802

process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Susannah Powell by email at Powell.susannah@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "James Parker", is written over a horizontal line.

James Parker, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

MASTER LABEL FOR EPA REG. No. 73314-25

Product Brand Name:
Optimize® FXC

Editorial Notes:

Bold, italicized text is information for the reader and not part of the label.

Bracketed text [] is optional text.

LCO Liquid Additive (EPA Registration No 73314-23) - Component A

ACTIVE INGREDIENT:

LCO MOR116:

D-Glucose, O-6-deoxy-2-O-methyl- α -L-galactopyranosyl-(1 \rightarrow 6)-O-[O-2-deoxy-2-[[[(11Z)-1-oxo-11-octadecen-1-yl]amino]- β -D-glucopyranosyl-(1 \rightarrow 4)-O-2-(acetylamino)-2-deoxy- β -D-glucopyranosyl-(1 \rightarrow 4)-O-2-(acetylamino)-2-deoxy- β -D-glucopyranosyl-(1 \rightarrow 4)-2-(acetylamino)-2-deoxy- β -D-glucopyranosyl-(1 \rightarrow 4)]-2-(acetylamino)-2-deoxy-

D-Glucose, O-2-deoxy-2-[[[(11Z)-1-oxo-11-octadecen-1-yl]amino]- β -D-glucopyranosyl-(1 \rightarrow 4)-O-2-(acetylamino)-2-deoxy- β -D-glucopyranosyl-(1 \rightarrow 4)-O-2-(acetylamino)-2-deoxy- β -D-glucopyranosyl-(1 \rightarrow 4)-O-2-(acetylamino)-2-deoxy- β -D-glucopyranosyl-(1 \rightarrow 4)-O-[6-deoxy- α -L-galactopyranosyl-(1 \rightarrow 6)]-2-(acetylamino)-2-deoxy-.....0.0000266%
OTHER INGREDIENTS > 99.9999734%
100.0000000%

Contains 0.0000029 pounds LCO MOR116 per U.S. gallon (0.00035 grams AI/liter)

Liquid Microbial Inoculant Product – Component B [*Fertilizer Component*]

Contains Non-plant Food Ingredients

Inoculant Guarantee

Bradyrhizobium japonicum.....<1%*
OTHER INGREDIENT: Aqueous carrier.....>99%
100%

*Contains a minimum of 10 billion (1x10¹⁰ CFU/g)

EPA Reg. No. 73314-25 EPA Est. No. [*Enter appropriate EPA establishment no.*]

NET CONTENTS: [*Allow blank space for fill in*]

LOT NO. [*Allow blank space for fill in*]

Liquid Microbial Inoculant Product [Expiration][Exp.][Expiry] Date: Not for sale or use after
[*Expiration date to be inserted*].

Manufactured for and guaranteed by:

Novozymes BioAg Inc.

3101 W. Custer Ave

Milwaukee, WI 53209

1800-245-4104

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.• Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye.
HOTLINE NUMBER In case of an emergency involving this product, or for medical assistance, call collect, day or night, (314) 694-4000. For product use information call: 1-877-775-8787	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

USER SAFETY RECOMMENDATIONS
<ul style="list-style-type: none">• Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.• Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Personal Protective Equipment (PPE)

All mixers, loaders, applicators, and other handlers must wear chemical resistant gloves, long-sleeved shirt, long pants, and shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Environmental Hazards

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

Read the entire label before using this product.

It is a violation of US Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State and Tribe, consult the State/Tribe agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS STATEMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:

- long-sleeved shirt and long pants
- shoes plus socks

Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.

Product Description

Optimize® FXC contains two components (A and B) in separate containers, combining LCO Liquid Additive (EPA Reg. No. 73314-23) with an industry approved *Bradyrhizobia* inoculant.

Component A contains the LCO in Optimize® FXC and has multiple modes of action that stimulate the growth of plant roots. When used in combination with *Bradyrhizobium japonicum*, Optimize® FXC promotes nodulation and colonization of *Bradyrhizobium japonicum* on the root. Additionally, Optimize® FXC stimulates germination of mycorrhizal spores and promotes mycorrhizal symbiosis in the root zone. Mycorrhizae are beneficial fungi that colonize plant roots and can form networks in the soil. Plant roots recognize LCO and other signals produced by the germinating mycorrhizal spores and *Bradyrhizobium* to stimulate root growth. Increased root growth can provide improved access to soil nutrients including nitrogen and water. These modes of action support the growth and yield potential of the crop.

- Promotes nodulation and colonization of *Bradyrhizobium* on the root
- Stimulates germination of mycorrhizal spores
- Enhances interactions between plant roots and microbes which increases root growth as well as nutrient and water uptake through the roots
- Increases yield potential
- LCO increases root mass and branching within the plant thereby providing potential enhanced root establishment and yield enhancement through additional nutrient uptake.

Component B is a liquid microbial inoculant that contains *Bradyrhizobium japonicum*. *Bradyrhizobium japonicum* forms root nodules which convert, or fix, nitrogen in the air into forms the plant can use. When combined in Optimize FXC, the LCO and *Bradyrhizobium japonicum* combine multiple modes of action to increase yield potential.

USE INSTRUCTIONS

Optimize® FXC combines LCO Liquid Additive (component A) with a liquid microbial inoculant containing *Bradyrhizobium japonicum* (component B). The [BOTTLE SIZE] bottle of component A, containing LCO, is intended to be mixed together with the [BLADDER SIZE] bladder of component B inoculant containing *Bradyrhizobium japonicum* to treat [XXX units] of soybean seed. Mix the entire contents of components A and B prior to application.

Application Rate

- Apply at a rate of 1.5 fl oz/100 lb seed (44.4 ml/45.4 kg).

For Best Results

- Open package only when ready to use.
- Plant within 120 days of adding to bare soybean seed.

Additional practices may be recommended for certain situations, see 'Seed Treatment Recommendations' section below.

Directions for Use for Continuous Application

- Start preparation of the Optimize® FXC only when you are ready to apply to seed.
- To ensure an even suspension shake the Liquid Bladder (component B) well. Settling of bacteria during storage is normal.
- Add LCO Liquid Additive (component A) into the Liquid Bladder, which contains the inoculants. Close the Liquid Bladder cap and agitate the premix.
- Pour the contents of the Liquid Bladder into the inoculant slurry tank.
- Alternatively mix the bladder contents and liquid additive together in a dedicated inoculant slurry tank
- Only prepare enough material that you can treat in a standard work day.
- Apply to the seed as soon as possible.
- Calibrate the system to ensure that 1.5 fl oz (44.4 ml) of Optimize® FXC flows out of the nozzle in the time that 100 lb (45.4 kg) of seed passes beneath it.
- For retail application only.

Seed Treatment Recommendations

- We do not recommend the use of additional water, polymers, or dyes beyond what is required with the seed treatment. If Optimize® FXC is applied to bare seed without other seed treatment products, non-chlorinated water may need to be added to Optimize® FXC, and the slurry applied at 3.0 fl oz/cwt. No additional carrier is needed if applied with approved seed treatment products.

TANK MIX COMPATIBILITY: Optimize® FXC contains viable *Bradyrhizobium japonicum*. Avoid mixing with other seed treatments as viability may be impacted. Visit www.novozymesbioag.com for a list of compatible seed treatment products.

CHEMICAL COMPATIBILITY: Optimize® FXC is physically and biologically compatible with a wide range of seed treatments when applied simultaneously or sequentially to the seed. However, application with other seed treatments may reduce the Optimize® FXC planting window. If additional seed treatments are required when applying, contact your dealer or Novozymes BioAg, Inc for specific recommendations. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

Additional practices may be recommended for certain situations including planting on land previously used for pasture, planting soybeans for the first time or other conditions that may limit nodulation. Double inoculation or other practices may be recommended in these situations for best results. For additional information please contact your supplier or visit www.novozymesbioag.com.

Double inoculation, the act of using a double application of a rhizobial inoculant, is recommended in certain soil conditions (such as when planting on land previously used for pasture or planting soybean for the first time). Double inoculation can be achieved by application of any combination of liquids, peat powders, or furrow-applied liquid or granule rhizobial inoculants that are labeled for the target crop. For additional information, please see www.novozymesbioag.com

SEED DYING

All seed commercially treated with this product must be adequately dyed with a suitable color to prevent accidental use as food for humans or feed for animals. Use an EPA-approved dye or colorant that imparts an unnatural color to the seed. Any dye or colorant added to treated seed must be cleared for use pursuant to 40 CFR, Part 153.155.

SEED LABELING

The user is responsible for ensuring that the treated seed container meets all of the requirements under the Federal Seed Act. The Federal Seed Act requires that the container of seed treated with Optimize® FXC must be labeled with the following statements:

- This seed has been treated with LCO MOR116.
- Do not use treated seed for food, feed or oil production.

The US Environmental Protection Agency also requires the following statements on the container of seed treated with Optimize® FXC:

- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.
- Store treated seed away from food and feed, and do not allow access by children, pets, or livestock. Do not reuse empty seed containers.
- Surplus treated seed or empty seed containers should be stored or disposed according to local requirements.

- Do not contaminate bodies of water when disposing of excess treated seed or wash waters from planting equipment.

CROP ROTATION

There are no restrictions on crop rotation. All crops can be replanted immediately without restrictions.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

PESTICIDE STORAGE: Store in original container away from feed and food. Store in a cool, dry place. Do not store in direct sunlight.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

CONTAINER HANDLING AND DISPOSAL: Non-refillable container (5 gallons (19 liters) or less). Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse as follows:** empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. **Pressure rinse as follows:** Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, by incineration, or by other procedures allowed by state and local authorities.

LIMITS OF LIABILITY AND WARRANTY

Novozymes BioAg Inc. warrants that this product is reasonably fit for the purposes set forth in the DIRECTIONS FOR USE ("Directions") when used in accordance with those Directions under the conditions described therein. This warranty is also subject to the inherent risks, conditions and limitations stated herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE, INFRINGEMENT (ALONE OR IN COMBINATION WITH OTHER REGISTERED PRODUCTS) OR MERCHANTABILITY IS MADE.

To the extent consistent with applicable law, buyer and all users are responsible for all loss or damage from use or handling of the product that results from conditions beyond the control of Novozymes BioAg Inc., including, but not limited to, crop injury, ineffectiveness due to such factors as weather conditions at planting, environmental conditions during seed storage, presence of other materials, seed of low quality or low vigor or low germination, or other unintended consequences that may result because of the manner of use or application inconsistent with that set forth in the Directions. Novozymes does not warrant any product reformulated or repackaged from this product except in accordance with Novozymes BioAg Inc. stewardship requirements and with Novozymes BioAg Inc. express written permission.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF NOVOZYMES BIOAG INC. OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF NOVOZYMES OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED PURCHASE, REPLACEMENT OF SUCH QUANTITY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL NOVOZYMES BIOAG INC. OR ANY OTHER SELLER OF THE PRODUCT BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES.

Upon opening and using this product, buyer and all users are deemed to have accepted the terms of this LIMITS OF LIABILITY AND WARRANTY that may not be varied by any verbal or written agreement. If terms are not acceptable, return at once unopened.

[Note to reviewer the following text will be added to certain state market labels] [Information regarding the contents and levels of metals in this product is available on the internet at: <http://www.aapfco.org/metals.html>]

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[NOVOZYMES RETHINK TOMORROW] [LOGO]

[Print Plate Number]